Attorney Docket No.: 6520.200-US
Serial No.: 10/619,237
Filed: July 14, 2003
Title: Medical Delivery Device
Via Facsimile No.: 571-273-8300

REMARKS:

Amendments to claims

New claim 30 corresponds to cancelled claim 24 with the following further limitations being added:

"[T]he delivery device comprising a lower surface provided with adhesive means and adapted to be arranged against and attached to a skin surface of the patient" and "attaching the delivery device to a skin surface of the patient" is based on the disclosure on page 6, lines 16-18 of the originally filed specification.

"[R]emoving the delivery device from the skin surface of the patient" and "wherein no delivery device is attached to a skin surface of the patient during a period between two periods of sleep of approximately 7-9 hours" " is based on the disclosure on page 5, lines 21-23 of the originally filed specification.

"Wherein the fluid communication is established at a time after which the patient is expected to sleep for a period of approximately 7-9 hours, the drug being infused substantially corresponding to the period of sleep" is based on previous claim 26.

New claim 31 corresponds to cancelled claim 27, new claim 33 corresponds to cancelled claim 25, and new claim 34 corresponds to cancelled claim 28.

New claim 32 is based on the disclosure on page 7, lines 12-17 of the originally filed specification.

No other amendments have been made to the claims.

Claim rejections – 35 USC 103

The examiner has rejected now cancelled claims 24-29 under 35 USC 103 as being unpatentable over Gross et al, US patent 5,848,991 in view of Berner et al, US patent publication 2003/0104052.

Gross et al states that the disclosed drug delivery device "may comprise a microprocessor which controls the delivery such that the rate of delivery is varied during a 24 hour cycle as is necessary due to the differing requirements of drug dosage during periods of activity, inactivity and sleep, and taking account of the subject's requirements in relation to food intake", see column 4, lines 55-63. In other words, the Gross et al device may be in the form of an "advanced" drug delivery device providing the same programmability as the type of pumps mostly used for the treatment of Type 1 diabetes, e.g. as supplied by Medtronic.

In the next paragraph it is stated that "Alternatively (emphasis added), the subject may be provided with separate daytime and nighttime devices".

As follows from this, Gross et al teaches that instead of a more complex device comprising a microprocessor, the patient may be supplied with two separate devices each having a different electronic circuit for controlling the time and rate of drug delivery for daytime respectively nighttime use, this allowing a patient to wear a device during all 24 hours of the day, albeit in the form of one device during daytime and another device during nighttime.

In contrast, new Claim 30 defines that the delivery device is attached to a patient only during nighttime.

In Gross et al, it is disclosed that the device may be used to deliver a number of different drugs, see column 6, line 42 to column 7, line 21, and it may thus be argued that the Gross et al device may be used for periods of different length and for different infusion rates. However, there is no disclosure or teaching that any given type of drug should be infused during 7-9 hours and during a period of sleep. And most specifically, there is no disclosure or teaching that insulin should be infused during 7-9 hours and during a period of sleep only as defined in new claim 32.

In contrast, applicant submits that when insulin is administered using a drug delivery device (i.e. in the form of a traditional type pump as provided by e.g. Medtronic) this is done solely for the treatment of patients suffering from diabetes Type 1 and thus for 24 hours. Treating diabetes patients with a body mounted drug delivery device with insulin during nighttime only is in contrast to all known regiments for the treatment of diabetes using a pump device.

In respect of the 7-9 hours limitation, the Examiner has cited Berner et al, paragraph 0126, however, this document is concerned with gastric delivery of calcium carbonate. Although Berner et al discloses that calcium carbonate may be delivered to the gastro-intestinal tract during 4-9 hours, applicant submits that this does not provide the skilled person with a teaching that insulin or any other drug should be administered to a patient during a period of 7-9 hours only using a skin mounted device.

That the present invention as defined in new claim 30 represents a special selection of properties and ranges (i.e. delivery of insulin to a patient using a pump device during nighttime only) providing special advantages associated with the selected properties and ranges is discussed in applicants reply dated April 17, 2006 to which reference is made.

Conclusion

In conclusion, Gross et al alone or in view of any of the references on file fails to make obvious to the skilled person a method as defined in new claim 30.

All further claims are dependent upon an independent claim.

In view of the above, applicants respectfully submit that all claims are in condition for allowance.

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The Commissioner is hereby authorized to charge any fees, including fees for extensions of time, in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. Should the Examiner have any questions or concerns, she should feel free to contact the applicants' attorney to discuss them.

Respectfully submitted,

Date: December 19, 2006

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